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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/605,498	10/02/2003	Martin Gleave	UBC.P-031	2497

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EXAMINER	
BOWMAN, AMY HUDSON	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/605,498	GLEAVE ET AL.	
	Examiner	Art Unit	
	Amy H. Bowman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *1-13,18 and 20-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-17, 19 and 25-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/12/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 8/12/2005 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 5/12/2005 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 8/12/2005, claims 1-28 are pending in the application. Claims 1-13, 18 and 20-24 have been withdrawn from consideration.

Response to Arguments--Claim Rejections - 35 USC § 102(b)

Claims 14-17, 19 and 25-28 stand rejected under 35 U.S.C. 102(b) as being anticipated by Baracchini et al. (US 5,801,154), for the reasons of record set forth in the office action mailed 5/12/05.

Applicant argues that Baracchini et al. do not disclose any oligonucleotide that is complementary to SEQ ID NO: 91. Applicant further argues that there is no oligonucleotide in Baracchini et al. that has a "consecutive series of bases" that is the same as in SEQ ID NO: 82. Applicant asserts that the SEQ ID NO: 6 of Baracchini et al. cited by the examiner clearly has no similarity.

Applicant's argument has been considered but is not found persuasive. Contrary to applicant's assertions, SEQ ID NO: 6 of Baracchini et al. meets the structural limitations of the instant claims. As explained in the office action mailed 5/12/05, Baracchini et al. teach antisense oligonucleotides comprising a consecutive series of bases as set forth in instant SEQ ID NO: 82. See for example, SEQ ID NO: 6, comprises a consecutive series of bases (bases 1-4, 8-10, and 12-15) as set forth in instant SEQ ID NO: 82 (bases 14-16, 18-20, and 8-11, respectively). Therefore, SEQ ID NO: 6 of Baracchini et al. comprises three consecutive series of bases as set forth in instant SEQ ID NO: 82. Contrary to applicants assertion that the sequences clearly have no similarity, applicant has not explained how bases 1-4 for example of SEQ ID NO: 6 of Baracchini et al. are not a consecutive series of bases as set forth in bases 14-16 of instant SEQ ID NO: 82. Since SEQ ID NO: 6 of Baracchini et al. comprises a consecutive series of bases as set forth in instant SEQ ID NO: 82, SEQ ID NO: 6 of Baracchini et al. also has "a sequence" complementary to a portion of SEQ ID NO: 91, as instantly claimed. Additionally, as explained in the office action mailed 5/12/05, although the oligonucleotides taught by Baracchini et al. are not specifically disclosed as compounds that reduce the amount of active *hsp27*, the oligonucleotides taught by Baracchini et al. meet the structural limitations of the instant claims and would therefore necessarily possess the ability to reduce the amount of active hsp27 as instantly claimed. As stated in the MPEP (see MPEP 2112), something that is old does not become patentable upon the discovery of a new property.

Therefore, the 35 U.S.C. 102(b) rejection set forth in the official office action mailed on 5/12/05 is considered proper and maintained.

Response to Arguments--Claim Rejections - 35 USC § 103(a)

Claims 14-17, 19 and 25-28, stand rejected under 35 U.S.C. 103(a), as being unpatentable over Horman et al., in view of Taylor et al., Baracchini et al. (US 5,801,154), and Bennett et al. (US 5,998,148), for the reasons of record set forth in the office action mailed 5/12/05.

Applicant points out that no reference as identifiable as "Taylor et al." was provided in the office action or listed on a PTO-892 form. Applicant argues that if the rejection is maintained, it should be a non-final action in which the reference is fully identified and provided. Applicant states that from the examiner's remarks, however, it appears that Taylor et al. is not specific to hsp27 and is, like Baracchini et al. and Bennett et al., only related to antisense technology generally. It appears that applicant understands the portion of Taylor et al. explained in the office action mailed 5/12/05 and relied upon by the examiner. Applicants were afforded an opportunity to request a copy of the reference that was inadvertently omitted from the 892. The examiner apologizes and a copy is provided along with an updated 892 form herein. Although the Taylor et al. reference is important to the rejection, Taylor et al. is simply a supporting reference and applicant has not provided a reason for rebuttal to the prima facie case involving the statement relied upon from the Taylor et al. reference.

Applicant argues that there must be knowledge in the art of a therapeutic utility in order for it to be obvious to place something in a pharmaceutical composition. Applicant further argues that Horman et al. do not teach antisense oligonucleotides of the instant invention, but teach using a full length anti-hsp27 antisense of which copies are made *in vivo*. Applicant asserts that the examiner's generalized teachings about making antisense oligonucleotides are not sufficient to render the claims obvious. Applicant argues that the examiner's statement of the content of Taylor et al. is inconsistent with the knowledge in the art because merely knowing the sequence of a cDNA does not render antisense oligonucleotides obvious because not all possible oligonucleotides are effective as antisense.

As stated in the office action mailed 5/12/05, Horman et al. teach that hsp27 is overexpressed in pre-malignant or malignant lesions and Horman et al. further teach antisense inhibition of hsp27. Contrary to applicant's assertion regarding there needing to be knowledge of a therapeutic utility, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). Horman et al. is relied upon for a desire to inhibit hsp27 in the art and further for the teaching of the role of hsp27 in pre-malignant or malignant lesions, indicating motivation

to specifically target and inhibit the hsp27 gene. Additionally, the generalized teachings cited in the antisense oligonucleotide art teach the simplicity of designing antisense oligonucleotides to known target genes. The examiner did not rely on Horman et al. for the usage of antisense oligonucleotides, but rather for the fact that hsp27 was a known target gene for inhibition, whether it be by antisense oligonucleotides or by other means, prior to the instant invention. The generalized teachings referred to by applicant support that antisense oligonucleotides are obvious means to inhibit the expression of a known gene and can be designed and screened for activity with simplicity. Contrary to applicants assertion that the examiner's statement of the content of Taylor et al. is inconsistent with the knowledge in the art because merely knowing the sequence of a cDNA does not render antisense oligonucleotides obvious because not all possible oligonucleotides are effective as antisense, the examiner did not assert that Taylor et al. teaches that merely knowing the cDNA sequence renders which specific oligos are effective as antisense. As stated in the office action mailed 5/12/05, Taylor et al. teach "that antisense oligonucleotides 7-30 nucleotides long can be synthesized to inhibit the expression of any protein provided the cDNA sequence is known. Taylor et al. also indicate that making and using such oligos are available to those of ordinary skill in the art, that it is common practice to chemically modify the such oligonucleotides to prolong their bioactivity, and also teach that with software analysis and high affinity oligos, one needs to screen only 3-6 oligos to find one that inhibits its target 66-95% (p. 565)." Therefore, Taylor et al. teaches that a screening process is commonly available to determine which oligos are functional as antisense. This is consistent with the teaching

of the instant specification, paragraph 19, that discloses "the cDNA sequence forms the basis for the development of antisense oligonucleotides."

Therefore, the 35 U.S.C. 103(a) rejection set forth in the official office action mailed on 5/12/05 is considered proper and maintained.

New Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14, 15, 17 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (Biochem Biophys Res Commun. 2001 Jun 8; 284(2): 261-7).

The invention of the above claims is drawn to a pharmaceutical composition comprising a therapeutic agent, more specifically an antisense oligonucleotide 12 to 35 nucleotides long that reduces the amount of active hsp27 in cancerous cells and a pharmaceutically acceptable carrier. The antisense oligonucleotide has a sequence complementary to a portion of SEQ ID NO: 91. The invention is further drawn to antisense oligonucleotide comprising a consecutive series of bases as set forth in SEQ ID NO: 82. The language "comprising a consecutive series of bases" is being interpreted as referring to comprising any consecutive series of bases in any portion of SEQ ID NO: 82.

Lee et al. teach an antisense oligonucleotide 18 nucleotides in length having a sequence complementary to a portion of SEQ ID NO: 91 (see for example nucleotides 12-15 of Lee et al. which are complementary to nucleotides 45-48 of instant SEQ ID NO: 91). The antisense oligonucleotide sequences targeted to hsp27 taught by Lee et al. is disclosed on page 262 of Lee et al. Additionally, the antisense oligonucleotide targeted to hsp27 taught by Lee et al. comprises a consecutive series of bases as set forth in instant SEQ ID NO: 82 (see nucleotides 3-6 of Lee et al. which are a consecutive series of bases as set forth as nucleotides 17-20 of instant SEQ ID NO: 82). Lee et al. teach compositions comprising the antisense oligonucleotide and buffers that are considered pharmaceutically acceptable (see page 262). The antisense oligonucleotide taught by Lee et al. meets the structural limitations of the instant claims and would therefore necessarily possess the ability to reduce the amount of active hsp27 in cancerous cells as instantly claimed. As stated in the MPEP (see MPEP 2112), something that is old does not become patentable upon the discovery of a new property.

Therefore, claims 14, 15, 17 and 19 are anticipated by Lee et al.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is 571-272-0755.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Amy H. Bowman
Examiner
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